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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WIEKER, AMANDA FLYNN

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/795,892	Applicant(s) BONUTTI ET AL.	
	Examiner Amanda F. Wieker	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-28 is/are rejected.
- 7) ☒ Claim(s) 16, 29-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the articulately mounted second cuff (claim 8); the articulately mounted hand pad (claim 17); and the locking assembly (claim 23) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the

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filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification lacks antecedent basis for the subject matter of claims 8 and 17.

4. The abstract of the disclosure is objected to because the phrase "The present invention provides" should be deleted because it is redundant and can be inferred from the abstract. Correction is required. See MPEP § 608.01(b).

Claim Objections

5. Claims 13 and 21 are objected to because of the following informalities:

In line 1 of claim 13 it appears that the word "removable" should be replaced with --removably--.

In line 1 of claim 21, the term "manualably" is unknown. It is suggested that this term be replaced with --manually--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 8 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 8 and 17 recite that the second cuff/hand pad is mounted to the second arm member "articulatingly". This has not been described in the specification sufficiently to allow one skilled in the art to make and/or use the invention. The specification discloses a second cuff/hand pad (34, 38) attached to the second arm member (14). The specification further discloses that the cuff/hand pad may be slidable on the arm. However, the specification does not disclose that the cuff/hand pad is articulatingly mounted on the arm, and such a mounting appears contrary to the desired function of the cuff/hand pad. The function of the second cuff/hand pad is to secure the body portion to the second arm member and allow sliding movement thereon, such that the cuff/hand pad is fastened tightly enough around the body portion, so that the second arm member may apply force to the second body portion without having the cuff/hand pad slide along the body portion. Such an articulating arrangement would seem to introduce an amount of movement and instability not allowed by the disclosed embodiment of the device.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 18-21, 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent Number 6,113,562 to Bonutti et al.

Bonutti et al. disclose an orthosis for stretching tissue around the shoulder and elbow joints of a patient between first and second relatively pivotable body portions (upper arm, lower arm), comprising:

a first arm member (150) affixable to the first body portion (upper arm) and including a first extension member (152) extending therefrom;

a second arm member (102) affixable to the second body portion and including a second extension member (240) having an arcuate shape extending therefrom, the second extension member (240) is operatively connected to the first extension member (152; see Figure 2) and travels along an arcuate path through the first extension member when the second arm member is moved from a first position to a second position relative to the first arm member.

Regarding claims 2-4, the orthosis further comprises a first cuff (160) attached to the first arm member (150). The first cuff is fastenable about the first body portion tightly enough that the first arm member may apply a force to the first body portion without having the first cuff slide along the first body portion. The first cuff is slidably mounted to the first arm member (cuff 160 affixed to 164, which is affixed to 154, which telescopically slides relative to 152).

Regarding claims 5-7, the orthosis further comprises a second cuff (126) attached to the second arm member (102). The second cuff is fastenable about the second body portion tightly enough that the second arm member may apply a force to the second body portion without having the second cuff slide along the second body portion. The second cuff is slidably

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mounted to the second arm member (cuff 126 affixed to 106, which telescopically slides relative to 104).

Regarding claim 8, the second cuff is considered to be “articulatingly” mounted to the second arm member. Inasmuch as Applicant has not defined or described this connection, the second cuff (126) is considered to articulate about second arm member (102), at fasteners (108). Cuff member (126) is capable of pivoting about the fasteners (108) as the lower arm is rotated.

Regarding claims 18-21, the orthosis further comprises a drive assembly (294, 296, 286, 284, 256) on the first extension member (152), the drive assembly engaging the second extension member (240) for selectively moving the second arm member with respect to the first arm member. The drive assembly includes a gear (256). The second extension member includes a plurality of teeth (250) for engaging the gear. The gear is manually rotatable (by 294) for selectively moving the second arm member with respect to the first.

Regarding claim 23, Bonutti et al. disclose a “locking assembly” that prevents movement of the gear absent rotation via the ratchet (see column 11, line 63 to column 12, line 6).

Regarding claims 24-29, the elbow joint defines a first plane substantially orthogonal to a longitudinal axis of the first arm member and a second plane substantially parallel to the longitudinal axis of the first arm member. The first extension member can extend from the first arm member, such that the operative connection of the first and second extension members can lie in the first plane, in front of the first plane or behind the first plane (see column 9, lines 43-55; “offset to one side”).

10. Claims 1-3, 5-6, 18-22, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,376,091 to Hotchkiss et al.

Hotchkiss et al. disclose an orthosis for stretching tissue around the shoulder and elbow joints of a patient between first and second relatively pivotable body portions (lower arm, upper arm), comprising:

a first arm member (40; right side in Figure 14) affixable to the first body portion (lower arm) and including a first extension member (32) extending therefrom;

a second arm member (40; left side in Figure 14) affixable to the second body portion and including a second extension member (30) having an arcuate shape extending therefrom, the second extension member (30) is operatively connected to the first extension member (32; see Figure 16) and travels along an arcuate path through the first extension member when the second arm member is moved from a first position to a second position relative to the first arm member.

Regarding claims 2-3, the orthosis further comprises a first cuff (38) attached to the first arm member (40R). The first cuff is fastenable about the first body portion tightly enough that the first arm member may apply a force to the first body portion without having the first cuff slide along the first body portion.

Regarding claims 5-6, the orthosis further comprises a second cuff (58) attached to the second arm member (40L). The second cuff is fastenable about the second body portion tightly enough that the second arm member may apply a force to the second body portion without having the second cuff slide along the second body portion.

Regarding claims 18-22, the orthosis further comprises a drive assembly (72, 76, 74) on the first extension member (32), the drive assembly engaging the second extension member (30) for selectively moving the second arm member with respect to the first arm member. The drive assembly includes a gear (74). The second extension member includes a plurality of teeth (see

Figures 14-16) for engaging the gear. The gear is manually rotatable (by 76), or controlled by a motor (see column 6, 1st paragraph), for selectively moving the second arm member with respect to the first.

Regarding claims 24 and 26, the elbow joint defines a first plane substantially orthogonal to a longitudinal axis of the first arm member and a second plane substantially parallel to the longitudinal axis of the first arm member. The first extension member can extend from the first arm member, such that the operative connection of the first and second extension members can be in front of the first plane.

11. Claims 1-3, 5-6, 8-15, 18-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,848,979 to Bonutti et al.

Bonutti et al. disclose an orthosis for stretching tissue around a joint of a patient between first and second relatively pivotable body portions (lower arm, hand), comprising:

a first arm member (24, 26) affixable to the first body portion (lower arm) and including a first extension member (158) extending therefrom;

a second arm member (110/112) affixable to the second body portion and including a second extension member (48) having an arcuate shape extending therefrom, the second extension member (48) is operatively connected to the first extension member (158) and travels along an arcuate path through the first extension member when the second arm member is moved from a first position to a second position relative to the first arm member.

Regarding claims 2-3, the orthosis further comprises first cuffs (44, 136) attached to the first arm member (24, 26). The first cuff is fastenable about the first body portion tightly enough that the first arm member may apply a force to the first body portion without having the first cuff slide along the first body portion.

Regarding claims 5-6, the orthosis further comprises a second cuff (122, 130) attached to the second arm member (110/112). The second cuff is fastenable about the second body portion tightly enough that the second arm member may apply a force to the second body portion without having the second cuff slide along the second body portion.

Regarding claim 8, the second cuff is considered to be "articulatingly" mounted to the second arm member. Inasmuch as Applicant has not defined or described this connection, the second cuff (126) is considered to articulate about second arm member (102), at rivets. Cuff member (126) is capable of pivoting about the rivets cuff is released.

Regarding claims 9-15, the second arm includes a hand pad (123) attached to the arm. The second body portion is a hand of the patient and the hand pad is fastenable about the hand of the patient tightly enough that the second arm member may apply a force to the hand of the patient without having the hand pad slide along the hand of the patient. The hand pad includes a convex surface for engaging a palm portion of the hand of the patient (see Figure 9; upper right portion of hand pad is convex). The hand pad includes a concave surface for engaging a back surface of the hand of the patient (see Figure 9; bottom of hand pad is convex). The hand pad is capable of being removed from the second arm member. The orthosis of claim 9, wherein the hand pad is slidably mounted to the second arm member. 17. The orthosis of claim 9, wherein the hand pad is articulatingly mounted to the second arm member.

Regarding claims 18-22, the orthosis further comprises a drive assembly (34) on the first extension member (158), the drive assembly engaging the second extension member (48) for selectively moving the second arm member with respect to the first arm member. The drive assembly includes a gear (56). The second extension member includes a plurality of teeth (219)

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for engaging the gear. The gear is manually rotatable (by 60) for selectively moving the second arm member with respect to the first. The orthosis further comprises a motor.

Regarding claim 23, Bonutti et al. disclose a "locking assembly" that prevents movement of the gear absent rotation via the knob.

Regarding claims 24-27, the elbow joint defines a first plane substantially orthogonal to a longitudinal axis of the first arm member and a second plane substantially parallel to the longitudinal axis of the first arm member. The first extension member can extend from the first arm member, such that the operative connection of the first and second extension members can lie in the first plane, in front of the first plane or behind the first plane (see horizontal movement permitted by 160, which allows operative connection at a variety of positions relative to said axis).

Regarding claim 28, the first extension member (158) is pivotably connected to at least part of the first arm member (26).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti et al in view of U.S. Patent Number 5,376,091 to Hotchkiss et al.

Bonutti et al. disclose an orthosis comprising a first arm member affixable to a first body portion and including a first extension member extending therefrom and a second arm member

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affixable to the second body portion and including a second extension member having an arcuate shape extending therefrom, wherein the second extension member is operatively connected to the first extension member and travels along an arcuate path through the first extension member when the second arm member is moved from a first position to a second position relative to the first arm member. Bonutti et al. further disclose a geared drive assembly for selectively moving the second arm member with respect to the first. Bonutti et al. do not specify that the drive assembly comprise a motor.

Hotchkiss et al. disclose an orthosis comprising a first arm member affixable to a first body portion and including a first extension member, and a second arm member affixable to the second body portion and including a second extension member having an arcuate shape extending therefrom, wherein the second extension member is operatively connected to the first extension member and travels along an arcuate path through the first extension member when the second arm member is moved from a first position to a second position relative to the first arm member. Hotchkiss et al. disclose a geared drive assembly wherein the gear is either manually rotated by a crank (76), or is driven by a motor, for effecting continuous passive motion to the joint.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the orthosis disclosed by Bonutti et al., wherein the gear is driven by a motor, as taught by Hotchkiss et al., to effect a continuous passive motion to the joint.

Allowable Subject Matter

14. Claims 16 and 29-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794.

The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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